OLR Bill Analysis

SB 21

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS.

SUMMARY:

By law, individual and group health insurance policies and HMO contracts must cover (1) medically necessary hospitalization services and other routine patient care costs associated with cancer clinical trials and (2) off-label cancer prescription drugs. This bill expands the coverage requirements to include all disabling, progressive, or life-threatening medical conditions rather than cancer only. (The bill does not define these terms.)

The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; and (4) hospital or medical services, including coverage under an HMO plan. Due to federal law (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

The bill also makes technical and conforming changes.

EFFECTIVE DATE: January 1, 2012

CLINICAL TRIALS

The bill defines a "clinical trial" as an organized, systemic, scientific study of interventions for the treatment of disabling, progressive, or life-threatening medical conditions, or therapeutic intervention for prevention. By law, a clinical trial for cancer prevention must be a Phase III trial conducted at multiple institutions. (Phase III clinical trials compare a new drug or surgical procedure to the current standard of treatment.) The bill does not require this for other types of

preventive clinical trials it covers, but maintains it for cancer clinical trials.

Eligibility for Coverage

By law, to be eligible for coverage, a cancer clinical trial must be conducted under an independent, peer-reviewed protocol approved by one of the National Institutes of Health, a National Cancer Institute-affiliated cooperative group, the federal Food and Drug Administration (FDA) as part of an investigational new drug or device exemption, or the U. S. departments of Defense or Veterans' Affairs. The bill applies this requirement to clinical trials for disabling, progressive, or life-threatening medical conditions. It also makes eligible for coverage clinical trials for disabling, progressive, or life-threatening medical conditions that qualify for Medicare coverage under the Medicare Clinical Trials Policy established under the September 19, 2000 Medicare National Coverage Determination.

The insurer, HMO, or plan administrator may require the person or entity seeking coverage for the clinical trial to provide:

1. evidence that the patient meets all selection criteria for the clinical trial, including credible clinical evidence showing the clinical trial is likely to benefit the person compared to the risks of participation;

2. evidence that the patient has given his or her informed consent;

3. copies of medical records, protocols, test results, or other clinical information used to enroll the patient in the clinical trial;

4. a summary of the anticipated routine patient costs in excess of the standard treatment costs;

5. information regarding items that are eligible for reimbursement from other sources, including the entity sponsoring the clinical trial; and

6. additional information reasonably required to review the

coverage request.

Routine Patient Care Costs

By law, and extended to all clinical trials by the bill, "routine patient care costs" are (1) medically necessary health care services, including physician services, diagnostic or laboratory tests, and hospitalization, incurred as a result of the treatment being provided that would otherwise be covered if they were not rendered as part of a clinical trial and (2) costs incurred for federal FDA-approved drugs. The services must be consistent with the usual and customary standard of care.

Hospitalization must include treatment at an out-of-network facility if such treatment is not available in-network and not eligible for reimbursement by the clinical trial.

Routine patient care costs must be subject to the terms, conditions, restrictions, exclusions, and limitations of the insurance contract or certificate, including limitations on out-of network care. But treatment at an out-of-network hospital must be made available by the out-of-network hospital and the insurer or HMO at no greater cost to the insured person than if such treatment was available in-network. The insurer or HMO may require that any routine tests or services required under the clinical trial be performed by contracted providers.

Routine patient care costs do not include:

1. the cost of an investigational new drug or device that is not FDA-approved;

2. the cost of a non-health-care service that an insured person may be required to receive as a result of the clinical trial;

3. facility, ancillary, professional services, and drug costs that are paid for by grants or funding for the clinical trial;

4. costs of services that are (a) inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis, or (b) performed specifically to meet the

requirements of the clinical trials;

5. costs that would not be covered under the insured person's policy for noninvestigational treatments, including items excluded from coverage under the person's insurance contract; and

6. transportation, lodging, food, or any other expenses associated with travel to or from the clinical trial facility.

Health care providers, including hospitals and institutions, that provide routine patient care services that are approved for coverage cannot bill the insurer, HMO, or insured for any (1) services or costs that do not meet the definition of routine patient care services or (2) product or service for which the clinical trial sponsor is paying.

Payment to Out-of-Network Providers

An insurer or HMO must pay out-of-network providers the lesser of (1) the lowest contracted daily fee schedule or case rate it pays its Connecticut in-network providers for similar services or (2) billed charges. Out-of-network providers are prohibited from collecting more than the total amount paid by the insurer or HMO and the insured's deductible and copayment.

Coverage Request Form

The bill requires the Insurance Department to develop a standardized form that all providers must submit to the insurer or HMO when seeking to enroll an insured patient in a clinical trial for a disabling, progressive, or life-threatening medical condition, excluding cancer. The department must develop the form in consultation with:

1. at least one state nonprofit research or advocacy organization related the clinical trial's subject,

2. at least one national nonprofit research or advocacy organization related to the clinical trial's subject,

3. the Connecticut Association of Health Plans, and

4. Anthem Blue Cross of Connecticut.

An insurer or HMO must use the department's form unless it is exempt because its coverage is certified to be substantially the same as the bill requires and it has the department's approval to use another form.

An insurer or HMO that receives a completed form from a provider requesting coverage for routine patient care costs for clinical trials other than cancer must approve or deny the request within five business days or, if using independent experts to review clinical trial requests, 10 business days. By law, requests for coverage of Phase III cancer clinical trials must be approved or denied within 14 business days.

Under existing law, the Insurance Department has to (1) develop a form for use with cancer clinical trials and (2) adopt regulations to implement the coverage request form requirements, which the bill extends to other clinical trials.

Exemption from Requirements

Insurers and HMOs must submit their coverage policies for clinical trials to the Insurance Department for evaluation and approval. The department must certify whether the coverage policy is substantially equivalent to the bill's requirements. If it is, the insurer or HMO is exempt from the bill's requirements.

An exempt insurer or HMO must annually report in writing to the department that there have been no changes to the coverage policy. If there have been changes, the insurer or HMO must resubmit the policy for the department's certification.

OFF-LABEL DRUGS

By law, individual and group health insurance policies that cover a prescription drug that is FDA-approved to treat a certain type of cancer must also cover the drug when it is used for another type of cancer if it is recognized as a cancer treatment in one of three sources (known as "off-label" drugs).

The bill also requires coverage for off-label drug use for FDA-approved drugs to treat other disabling, progressive, or life-threatening medical conditions. The drug must be recognized for the treatment of such a condition in the:

1. U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional,

2. American Medical Association's Drug Evaluations, or

3. American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information.

The bill specifies that it does not require coverage for experimental or investigational drugs or any drug that the FDA has determined to be contraindicated for the treatment of a specific disabling, progressive, or life-threatening medical condition. This is already law with respect to cancer drugs.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 10 Nay 9 (02/10/2011)